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44. (New) A method for implantation of a self-expanding stent, the method comprising:

providing a delivery system including a self-expanding stent, a catheter having a distal end and being configured to retain the self-expanding stent proximate the distal end, an inflatable device provided on the catheter and positioned either between the self-expanding stent and the distal end or beneath a portion of the self-expanding stent;

delivering the delivery system to a region of a vessel to be repaired;
releasing a portion of the self-expanding stent to a position corresponding
with a marker band on the catheter;

re-constraining the self-expanding stent;

implanting the self-expanding stent into a wall of the vessel to be repaired;

and

stent.

inflating the inflatable device to assist expansion of the self-expanding

REMARKS

Claims 1-44 are pending in the application. By this Amendment, claims 1-3, 5, 7-9, 11-14, 16, and 17 have been amended, and new claims 29-44 have been added. No new matter has been added. Applicant respectfully requests reconsideration and allowance of the pending claims.

Initially, Applicant thanks Examiner Landrem for indicating that claims 5 and 6 would be allowable if rewritten in independent form.

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In the Office Action, claims 1-4, 7, 8, 11-18, and 20-28 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,743,874 to Fischell et al. (Fischell). In addition, claims 9 and 10 were rejected under 35 U.S.C. § 103(a) over Fischell in view of U.S. Patent No. 6,056,759 to Fiedler (Fiedler) and claim 19 was rejected under § 103(a) over Fischell in view of U.S. Patent No. 6,221,081 to Mikus et al. (Mikus). Applicant respectfully traverses these rejections.

Regarding claim 1, Fischell does not disclose or suggest a stent delivery system comprising, *inter alia*, "a tubular member including a first marker band proximate a position corresponding to a leading end of a self-expanding stent, a second marker band proximate a position corresponding to a trailing end of the self-expanding stent, and a third marker band between the first and second marker bands." Instead, Fischell discloses an integrated catheter including a proximal radiopaque marker 182 at a proximal end of a self-expanding stent and a distal radiopaque marker 180 at a distal end of the self-expanding stent. Fischell also discloses a radiopaque band 152 at a center of an interior chamber 151 of an inflatable balloon 150. The radiopaque band 152 is not between the proximal and distal radiopaque markers 180, 182. Therefore, Fischell does not disclose or suggest a tubular member having a first marker band, a second marker band, and a third marker band between the first and second marker bands, as recited in claim 1. Accordingly, the § 102(b) rejection of claim 1 should be withdrawn.

With respect to independent claim 17, <u>Fischell</u> does not disclose or suggest a method for implantation of a self-expanding stent including, *inter alia*, "providing a delivery system including a self-expanding stent, a catheter having a distal end and

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being configured to retain the self-expanding stent proximate the distal end, and an inflatable device provided on the catheter and positioned beneath at least a portion of the self-expanding stent." To the contrary, <u>Fischell</u> discloses an integrated catheter having, in one embodiment, a balloon 50 axially separated from a stent 60 by a marker band 80 and, in another embodiment, a balloon 150 axially separated from a stent 160 by a radiopaque marker 182. In either embodiment, <u>Fischell</u> does not disclose or suggest the balloon 50, 150 positioned beneath any portion of the stent 60, 160. Therefore, <u>Fischell</u> does not disclose or suggest an inflatable device provided on the catheter and positioned beneath at least a distal portion of the self-expanding stent, as recited in claim 17. Accordingly, the § 102(b) rejection of claim 17 should be withdrawn.

New independent claims 29, 36, and 44 are also patentable over <u>Fischell</u>. <u>Fischell</u> does not disclose or suggest, *inter alia*, an inflatable device provided on the catheter, wherein at least a portion of the self-expanding stent overlaps at least a portion of the inflatable device, as recited in claim 29; a loading funnel configured to be removably attachable to the distal end of the catheter, as recited in claim 36; and the steps of releasing a portion of the self-expanding stent to a position corresponding with a marker band on the catheter and re-constraining the self-expanding stent, as recited in claim 44.

<u>Fiedler</u> and <u>Mikus</u> fail to overcome the above-noted deficiencies of <u>Fischell</u>, and are not relied upon for overcoming these shortcomings. Accordingly, independent claims 1, 17, 29, 36, and 44 define patentable subject matter.

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Claims 2-16, 18-28, 30-35, and 37-43 depend from either claim 1, 17, 29, or 36 and are therefore allowable for at least the same reasons claims 1, 17, 29, or 36 are allowable.

The Office Action contains numerous characterizations of the invention, the claims, and the related art, with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

Applicant respectfully requests reconsideration of this application, withdrawal of the claim rejections, and timely allowance of the pending claims.

If the Examiner believes a telephone conversation might advance prosecution, the Examiner is invited to call Applicant's undersigned attorney at 202-408-4252.

If there are any fees due in connection with this submission, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: November 18, 2002

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APPENDIX

Comparison of Amended Claims to Originally-Filed Claims

IN THE CLAIMS:

Please amend claims 1-3, 5, 7-9, 11-14, 16, and 17 as follows:

 (Amended) A delivery system for a self-expanding stent, the delivery system comprising:

a catheter having a distal end, the catheter being configured to retain a self-expanding stent proximate the distal end, the catheter including

a tubular member including a first marker band proximate a position

corresponding to a leading end of a self-expanding stent, a second marker band

proximate a position corresponding to a trailing end of the self-expanding stent, and a

third marker band between the first and second marker bands, and

an outer member positioned about the tubular member; the outer member being slidable relative to the tubular member in an axial direction; and an inflatable device provided on the catheter and positioned proximate the distal end.

- 2. The [delivery system] <u>combination</u> of claim [1] <u>29</u>, wherein the catheter includes a tubular member and an outer member coaxially positioned about the tubular member, the outer member being slidable relative to the tubular member in an axial direction.
- 3. The delivery system of claim [2] 1, wherein the outer member is configured to retain a self-expanding stent in a radially-compressed position and to release the self-expanding stent to a radially-expanded position.

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- 5. The delivery system of claim [3] 1, further comprising a loading funnel, the loading funnel configured to be removably attachable to the distal end of the tubular member.
- 7. The delivery system of claim [2] 1, further comprising a spacing jacket coaxially positioned about the tubular member and inside the outer member.
- 8. The delivery system of claim [2] 1, further comprising a fluid port, the fluid port configured to receive a fluid and direct the fluid to a region between the tubular member and outer member.
- 9. The delivery system of claim [2] 1, wherein the distal end of the tubular member includes a tapered tip.
- 11. The delivery system of claim [2] 1, wherein the [tubular member includes a first marker band indicating a position corresponding to a proximal end of a self-expanding stent, a second] third marker band [indicating] indicates a position corresponding to a re-constrain limit of a partially-expanded, self-expanding stent [, and a third marker band indicating a position corresponding to a distal end of a self-expanding stent, the third marker band positioned nearest the distal end of the tubular member and the second marker band positioned between the first marker band and the third marker band].
- 12. The delivery system of claim [2] 1, wherein the tubular member defines a first lumen and a second lumen, one of the first lumen and the second lumen configured to receive a guidewire, and the other of the first lumen and the second lumen providing a fluid passage to the inflatable device.

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- 13. The delivery system of claim [2] 1, wherein [the distal end of the tubular member includes] at least one of the first, second, and third marker bands is a radiopaque marker [bands proximate positions corresponding to a leading end and a trailing end of a self-expanding stent] band.
- 14. The delivery system of claim [2] 1, further comprising a holding sleeve provided on the tubular member and configured to hold a self-expanding stent, the holding sleeve being spaced from the distal end of the catheter.
- 16. In combination, a self-expanding stent and a delivery system for the self-expanding stent, the combination comprising:

the delivery system of claim 1; and

a self-expanding stent mounted on the delivery system [;

a catheter having a distal end, the catheter being configured to retain the self-expanding stent proximate the distal end; and

an inflatable device provided on the catheter and positioned between the self-expanding stent and the distal end].

17. A method for implantation of a self-expanding stent, the method comprising:

providing a delivery system including a self-expanding stent, a catheter having a distal end and being configured to retain the self-expanding stent proximate the distal end, and an inflatable device provided on the catheter and positioned [either between the self-expanding stent and the distal end or] beneath <u>at least</u> a [distal] portion of the self-expanding stent;

delivering the delivery system to a region of a vessel to be repaired;

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implanting the self-expanding stent into a wall of the vessel to be repaired;

and

inflating the inflatable device to assist expansion of the self-expanding

stent.

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